

# PHARMACY INSPECTION

The Board of Pharmacy is updating the form that the Division of Drug Control will be using on routine annual inspections of community pharmacies to include reporting of compliance with a number of new regulations. Pharmacies will be receiving a 'pre-inspection form' prior to the visit to guide them to have answers and material readily available on the day of the inspection. This process should provide for a more meaningful review of compliance with laws and require a shorter time period than previous inspection. The most time consuming delays in the inspection process occur when the pharmacist on duty is not able to locate required documentation. Completion or retention of a completed form is voluntary and it is **not** to be sent to the Board. The form is both an educational tool and an expedient in the inspection process. Items, which have been added to the new inspection form, include compliance with the documentation required for regulations related to:

## [COMAR 10.34.03 Long Term Care Facilities](#)

- Policy and Procedure Manual
- Repackaging records if repackaging is done

## [COMAR 10.34.04 Transfer and Outsourcing](#)

- Documentation by primary pharmacy
- Documentation by secondary pharmacy

## [COMAR 10.34.16 Portable drug kits for home health agencies](#)

- Documentation kept when providing portable drug kits

## [COMAR 10.34.21 Unlicensed pharmacy personnel:](#)

- Policy & Procedures manual
- Training Manual
- Documentation of Training

## [COMAR 10.34.25 Delivery of Prescriptions](#)

- Delivery log

## [COMAR 10.34.26 Patient Safety Regulations](#)

- Quality Assurance programs for staff education
- Quality Assurance programs for error prevention

## [COMAR 10.34.28 Automation](#)

- System Failure reports
- Performance audits
- QA programs
- Level of Access Documentation
- Training records

HIPAA requirements such as naming Privacy and Security Officers (45CFR142.30, 164.530) If one or more type of record is kept off-site the inspector will note that and the pharmacist will be asked to acknowledge by signing the inspection form. Chains and other pharmacies that do keep records off-site are asked to let pharmacists on duty know where the information is kept. The Board, however, reserves the right to physically review these records. The above are only the highlights of some regulations that require pharmacy documentation and are provided as a guideline. It is not a complete list. Pharmacies that do not participate in practices such as outsourcing, long term care, delivery or automation will have n/a notations on the inspection. If you have any questions, please contact the Board of Pharmacy or the Division of Drug Control. [n](#)